REMARKS

Reconsideration and removal of the grounds for rejection are respectfully requested. Claims 10-18 and 20-28 were pending in the application, claims 10-18 were withdrawn, claims 1-9 and 19 were cancelled, and claims 20, 21, 25 and 28 have been amended.

Entry of this amendment after final is respectfully requested as placing the application in condition for allowance and/or reducing the issues on appeal. This amendment does not add any elements to claims 20, 21, 25 or 28. Rather, claim 20 is only amended to clarify the claim language relative to the microparticulates or microtablets being composed of granulated lithium salts and a binder, and clarifying the nature of the mixture of microgranules or microtablets. Claims 21 and 25 have been amended to correct errors, and claim 28 amended to be consistent with claim 20. A new search is not necessary nor are new issues raised by these amendments. It is also believed that the amendment renders moot the rejections over the prior art, placing the application in condition for allowance.

Claim 21 was rejected under 35 USC 112, first paragraph, for use of the term 1000 mg/g. This was an error in restating claim 2 as new claim 21, and this has been corrected to read "1000 mg per dose", as did original claim 2, and the rejection is believed to be moot.

Claims 20, 23, 24 and 26 were rejected as being anticipated by Gai et al. To anticipate, each and every element of the claim must be found in a single prior art reference. W.L. Gore & Associates, Inc. v. Garlock, Inc., 220, U.S.P.Q. 303 (Fed. Cir. 1983). Further, the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the art in possession of the invention. In re Spada, 15 U.S.P.Q.2d 1655 (Fed. Cir. 1990). An anticipatory reference must be enabling, containing adequate descriptions for practicing the applicant's invention. Akzo N.V. v. Intr'l Trade Comm., 1 U.S.P.Q.2d 1241 (Fed. Cir. 1986).

Anticipation requires a strict identity, without guessing what the reference discloses. In Dayco Products, Inc. V. Total Containment Inc., 329 F.3d 1358 (Fed. Cir. 2003), the Federal Circuit overruled an anticipation finding that a "polymeric" hose was found in the prior art stating:

> "On appeal, TCI admits that the reference fails to expressly state that the hose 18 of Lusher is a polymeric hose. Instead, TCI asserts

> that 'it is inherent from Figure 2 that the inner corrugated hose was made from a synthetic (i.e. polymeric) material.' (cite omitted). There is no support on the record before us for the proposition that Lusher (filed September 27, 1939), necessarily disclosed the use of a polymeric material. 'To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence; however such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference.' " Cont'l Can Co. USA v. Monsato Co., 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). TCI has cited to no evidence that this missing element was necessarily present.

Similarly here, Gai does not anticipate the applicants invention. Claim 20 is directed to a formulation containing a plurality of microgranules or microtablets, in a mixture containing modified release microparticles or microtablets and conventional release microgranules or microtablets. No such mixture of different release microgranules or microtables is found in Gai. Gai presents two separate formulations: "Two sustained release (SR) lithium carbonate (Li) matrix tablets ... have been studied." (P.131) "Two studies, one for each formulation, were conducted... ."(P.133) "Figures 1 and 2 show the mean dissolution profiles obtained for the HP and L tablets, respectively... ." "The difference between the two tablets in their behavior in gastric medium... ."(P. 134)

Nowhere in Gai is there the disclosure of a mixture on conventional release and modified release microparticles, as are present in the applicants' formulation, and claim 20, and the claims depending therefrom are not anticipated by Gai.

Claims 20, 22-24 and 26 were rejected as being anticipated under 35 USC 102(e) by Tarro. Enclosed herewith is a verified translation of the Italian priority document, which mirrors the present application, and so removes Tarro as prior art. This rejection is thus moot.

Claims 20, 24, 26-27 were rejected as being anticipated under 35 USC 102(b) by

Paradissis, EP 396425. Paradissis fails to disclose each and every element of claim 20.

Absolute identity is required for anticipation. While Paradissis discloses an extended release formulation, there is no specific disclosure of a formulation having a lithium salt content "of at least 500 mg/g" as required by claim 20. Consequently, claims 20, 24 and 26-27 are not anticipated thereby.

Claim 28 was rejected under 35 USC 103(a) as being obvious over Paradissis et al. To support a holding of obviousness, there must be some teaching or suggestion for doing as the applicant has done. ACS Hospital Systems Inc. v. Montefiore Hospital, 723 F.2d 1572 (Fed. Cir. 1984). Further, it is not within the framework of 35 U.S.C. Section 103 to pick and choose from the prior art only so much as will support a holding of obviousness to the exclusion of other parts necessary for a full appreciation of what the prior art teaches or suggests, as hindsight is not the test. In re Wesslau, 353 F.2d 238 (CCPA 1965). Also, "Both the suggestion and the expectation of success must be found in the prior art, not in the applicant's disclosure." In re Dow Chemical Co., 837 F.2d 469 (Fed. Cir. 1988).

Paradissis states "formulations of the present invention are composed of a mixture of 0 to 50% of an immediate release particle containing a core of drug, inert spherical substrate particles and binder, coated with talc and up to 100 % of an extended release particle comprising the immediate release particle coated with a dissolution modifying system containing plasticizers and a film forming agent, wherein the particle size of the extended release formulation is - 10 + 60 mesh." (Summary, l. 42-46).

The applicants invention does not utilize inert spherical particles, but rather requires microgranules or microtablets containing granulated lithium salts and a binder. This is described throughout the application, and in particular, see p.2, l. 20-26.

One skilled in the art referring to Paradissis would recognize that the inert spheres are necessary to prepare the "immediate release" particles, and so prepare the formulation by "a) forming a core material by spraying a solvent containing a dissolved binder onto a mixture of at least one drug and inert spherical particles; b) drying the resulting mixture to form a core material and coating the core material with talc; [then, to prepare the extended release particles,] c) coating the immediate release particles by spraying the particles with a dissolution modifying

system containing plasticizer and film forming agent to form an extended release pharmaceutical formulation; and d) recovering the formed extended release pharmaceutical formulation." (Summary, p.2, l. 51-p. 3, l. 2)

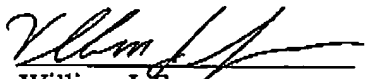
There is no teaching or suggestion for modifying the product of Paradissis by eliminating the inert spherical particles, in fact the contrary is true. The inert particles are needed to provide the "immediate release" property, as these "aid in the diffusion/release of the drug from the formulation", and these comprise a substantial proportion of the immediate release particles (from about 15 to about 40% by weight). (p. , l. 39-46) Consequently, granulated lithium salts with binder are not obtained, but rather inert spheres are first coated with a drug and binder, and then coated with talc.

There is no teaching or suggestion for producing the formulation of the applicants invention, and in fact one is led away from the use of a granulated lithium salt. Certainly there is nothing that would lead one to discard the inert sphere approach of Paradissis and so a different formulation would be produced, distinct from the applicants invention.

Certainly, there is no expectation of success that a dissolution profile of claim 28 could be achieved using the formulation of the applicants invention, which is easier to produce, and therefore less costly that the inert sphere based formulation of Paradissis. Consequently, none of claims 20-28 are believed rendered obvious over Paradissis.

Based upon the above amendments and remarks, favorable consideration and allowance of the application is respectfully requested. However, should the examiner believe that direct contact with the applicant's attorney would advance the prosecution of this application, the examiner is invited to telephone the undersigned at the number given below.

Respectfully submitted,



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